

### III. FY02: BPD Reports Submitted by Manufacturers of Biological Products Other Than Blood and Blood Components (Non-Blood)

The number of reports submitted by non-blood manufacturers increased by 19.6% from FY01 to FY02; with the greatest increase being in reports submitted by In-Vitro Diagnostic manufacturers. In-Vitro Diagnostic manufacturers submitted 28 reports in FY01 and 93 reports in FY02.

**Total BPDs By Manufacturing System**

MANUFACTURING SYSTEM	ALLERGENIC	DERIVATIVE	IN-VITRO DIAGNOSTIC	THERAPEUTIC	VACCINE	TOTAL	
Incoming Material	1	3	2	2	0	8	1.7%
Process Controls	0	7	30	7	10	54	11.3%
Testing	2	4	11	4	10	31	6.5%
Labeling	29	4	11	1	3	48	10.1%
Product Specifications	225	20	29	6	17	297	62.4%
Quality Control & Distribution	15	7	7	3	2	34	7.1%
Miscellaneous	1	0	3	0	0	4	0.8%
<i>Total</i>	273	45	93	23	42	476	100.0%

**Potential Recalls By Manufacturing System**

MANUFACTURING SYSTEM	ALLERGENIC	DERIVATIVE	IN-VITRO DIAGNOSTIC	THERAPEUTIC	VACCINE	TOTAL	
Incoming Material	0	1	0	0	0	1	2.5%
Process Controls	0	1	1	1	1	4	10.0%
Testing	1	0	0	1	0	2	5.0%
Labeling	12	1	4	0	0	17	42.5%
Product Specifications	0	2	7	2	3	14	35.0%
Quality Control & Distribution	1	0	0	0	0	1	2.5%
Miscellaneous	0	0	1	0	0	1	2.5%
<i>Total</i>	14	5	13	4	4	40	100.0%

## NON-BLOOD MANUFACTURES

### Timeliness Of BPDs

#### Number Of Days From Date Bpd Discovered To FDA Received

CUMULATIVE PERCENT OF REPORTS	Allergenic (Days)	Derivative (Days)	In-Vitro Diagnostic (Days)	Therapeutic (Days)	Vaccine (Days)	TOTAL (Days)
10%	17	21	29	15	17	20
25%	27	28	39	41	24	28
50%	37	46	56	43	44	42
75%	54	54	171	50	50	61
90%	90	82	282	124	80	147
# REPORTS	273	45	92	23	42	475
RANGE	2-399	15-210	11-1409	12-634	9-303	2-1409
AVERAGE	53	54	126	78	51	68
# Reports lacking date discovered	0	0	1	0	0	1

### Adherence To 45 Day Required Time For Reporting

#### (Reporting Time = Date of FDA receipt – Date of discovery of BPD)

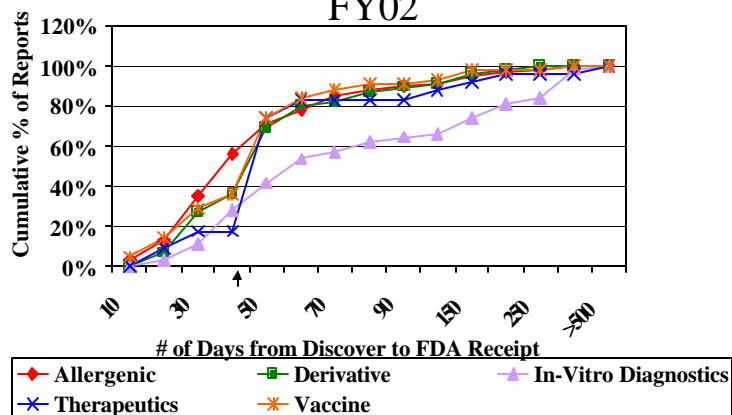
Reporting Time (days)	Allergenic		Derivatives		In-Vitro Diagnostics		Therapeutics		Vaccines		Total	
< or = 45	178	65.2%	20	44.4%	33	35.9%	12	52.2%	23	54.8%	266	56.0%
Between 45 and 90	67	24.5%	20	44.4%	26	28.3%	7	30.4%	15	35.7%	135	28.4%
> 90	28	10.3%	5	11.1%	33	35.9%	4	17.4%	4	9.5%	74	15.6%
Total	273	100.0%	45	100.0%	92	100.0%	23	100.0%	42	100.0%	475	100.0%

## Biological Product Deviation Reports

Non-Blood Manufacturers

Reporting Time - Total Reports

FY02



Total Reports = 475

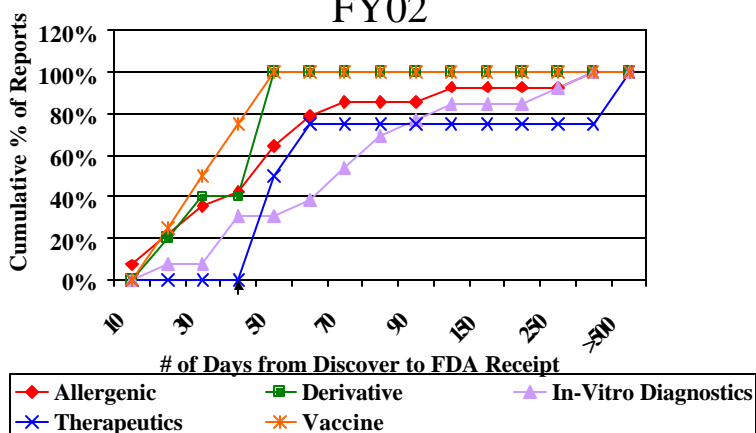
Allergenic=273; Derivatives=45; In-Vitro Diagnostics=92; Therapeutics=23; Vaccines=42

## Biological Product Deviation Reports

Non-Blood Manufacturers

Reporting Time – Potential Recalls

FY02



Total Reports = 40

Allergenic=14; Derivatives=5; In-Vitro Diagnostics=13; Therapeutics=4; Vaccines=4